

# 非吸收高分子结扎夹用连发施夹钳使用说明书

## IFU of Multiple Clip Reusable Applier

【产品名称 Product name】 非吸收高分子结扎夹用连发施夹钳 Multiple Clip Reusable Applier

【型号规格 Model specification】 MCA-12CL、MCA-10CM、MCA-10CS

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【生产企业许可证号 Production enterprise license number】

【注册证号 Registration number】

【产品技术要求编号 Product technical requirement number】

【产品结构组成 Product structure】 非吸收高分子结扎夹连发用施夹钳（以下简称连发施夹钳）由钳喙、关节、柄部组成。The Multiple Clip Reusable Applier(hereinafter referred to as the applier) is composed of a proboscis, a joint, and a handle.

【产品性能 Product performance】 连发施夹钳头部及杆部前端呈哑光色，不得有锋棱、裂纹、毛刺，杆部应平直。在旋转杆部时应顺利，杆部可 360° 自由旋转，且在旋转时应无干扰使用的晃动。The head of the applier and the front end of the rod are matte, without sharp edges, cracks, or burrs, and the rod should be straight. It should be smooth when rotating the rod, the rod can be rotated freely 360°, and there should be no shaking that interferes with use when rotating.

【适用范围 Scope of application】 本产品作为输送与钳闭器械，通过适配尺寸的穿刺套管可进行连续输送与钳闭连发用非吸收高分子结扎夹。This product is used as a delivery and clamping device, and can be used for continuous delivery and clamping through the puncture cannula of suitable size multiple polymer ligating clips.

【适配型号 Compatible model】

连发施夹钳型号规格 Specifications of applier	连发结扎夹型号规格 Specifications of multiple polymer ligating clips.	穿刺套管尺寸 Piercing cannula size
MCA-12CL	NLC-CL-2、NLC-CL-3、NLC-CL-4、 NLC-CL-5、NLC-CL-6	φ12mm
MCA-10CM	NLC-CM-2、NLC-CM-3、 NLC-CM-4、NLC-CM-5、NLC-CM-6	φ10mm
MCA-10CS	NLC-CS-2、NLC-CS-3、NLC-CS-4、 NLC-CS-5、NLC-CS-6	φ10mm

内部文件严禁外传

Internal documents are strictly prohibited from being circulated outside

【禁忌症 Contraindication】 无 None

【注意事项、警示及提示性说明 Precautions, Warnings and Instructions】

1. 产品应与本公司生产的《连发用非吸收高分子结扎夹》（以下简称连发结扎夹）配套进行施夹使用，使用前请确认连发结扎夹型号，并选择适配型号的连发施夹钳使用。The product is recommended to be used in conjunction with the "Multiple Polymer Ligating Clips" (hereinafter referred to as the ligating clip) produced by our company. Please confirm the model of the ligating clip before use, and choose the suitable type of applier for use.
2. 连发施夹钳使用后务必及时清洗灭菌，清洗灭菌过程无需拆解器械；The applier must be cleaned and sterilized in time after use, and there is no need to disassemble it during the cleaning and sterilization process;
3. 连发施夹钳的清洗灭菌避免使用腐蚀性溶剂；避免重压或撞击器械各部件。When cleaning and sterilizing applier, avoid the use of corrosive solvents, avoid heavy pressure or impact on various parts of the product;

【使用说明 Instructions for use】

1. 使用前检查 Check before use:

1.1 连发施夹钳应经过清洗灭菌并包装完好。Applier should be cleaned and sterilized and packaged in good condition.

1.2 连发施夹钳闭合时，钳头二片应对齐，不得有错位、摇晃现象。When the applier is closed, the two pieces of the applier's tip should be aligned, and there should be no misalignment or shaking.

2. 须由有经验的医护人员进行如下操作（结合图示详细阅读使用说明）The following operations must be performed by trained medical personnel (read the instructions for use in detail with the illustration):

2.1 应根据血管或管状组织尺寸，先选择合适的连发结扎夹规格型号，再选择适配的连发施夹钳规格型号；According to the size of blood vessels or tubular tissues, the appropriate ligating clip specification and model should be selected first, and then the suitable applier specification and model should be selected.

2.2 检查复位帽，应处于手柄末端位置；Check the resetting cap, which should be at the end of the handle;

2.3 扳动夹闭扳机使钳头闭合，检查钳头二片应相互吻合，不得有错位、摇晃现象；Pull the clamping trigger to close the applier's tip, and check that the tip of the applier head should match each other, and there must be no misalignment or shaking;

2.3 释放夹闭扳机使钳头复位，扳动输送扳机，可正常推进无阻塞；拉动复位帽，使之回到原位；Release the clamping trigger to reset the applier tip, pull the delivery trigger, it can be pushed normally without obstruction; pull the resetting cap to make it return to its original position;

2.4 往后扣动保险锁扣，将扣合后并拆除匣套的连发匣（带夹）装入安装仓内，扣合锁扣压紧连发匣。注意：连发匣的箭头标识应指向钳头；Pull the locking buckle, put the cartridge (with ligating clip) that has been buckled and removed the sleeve of cartridge, and buckle the lock buckle to compress the cartridge. Note: The arrow mark of the cartridge should point to the tip;

2.5 连发匣安装完成后，应视连发匣的装量差别，按以下规程操作：当连发匣 6 枚装时，输送扳机扳动 1 次，视窗数显为 6；当连发匣 5 枚装时，输送扳机扳动 2 次，视窗数

显为5；当连发匣4枚装时，输送扳机扳动3次，视窗数显为4；当连发匣3枚装时，输送扳机扳动4次，视窗数显为3；当连发匣2枚装时，输送扳机扳动5次，视窗数显为2。此时，连发施夹钳已进入备用状态；After the installation of the cartridge is completed, depending on the difference in the loading capacity of the cartridge, operate according to the following procedures: When the cartridge is loaded with 6 pieces, the delivery trigger is pulled once, and the digital display on the is 6; when the cartridge is loaded with 5 pieces, the delivery trigger is pulled twice, The window digital display is 5; when the cartridge is loaded with 4 pieces, the delivery trigger is pulled 3 times, and the window digital display is 4; when the cartridge is loaded with 3 pieces, the delivery trigger is pulled 4 times, the window digital display is 3; when the cartridge is installed with 2 pieces, The delivery trigger is pulled 5 times, and the digital display of the window is 2. At this point, the applier has entered the standby state;

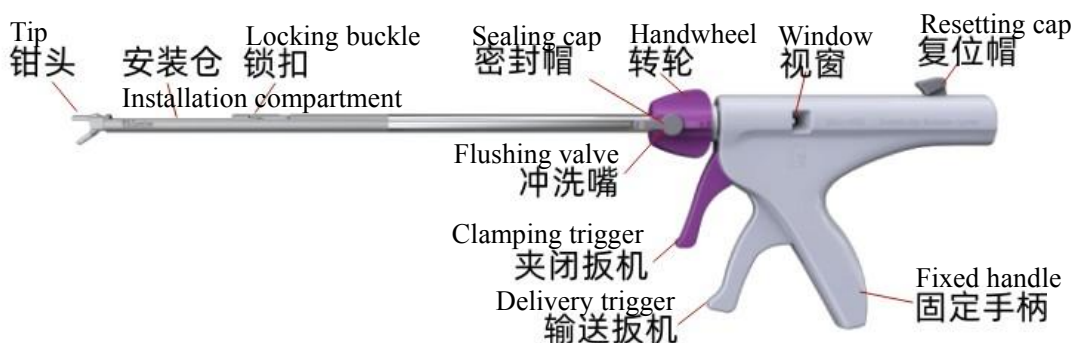
2.6 使用时，扳动夹闭扳机使钳口呈闭合状态，通过穿刺器进入腹腔，进入腹腔后松开夹闭扳机；When in use, pull the clamping trigger to close the tip, enter the abdominal cavity through the trocar, and release the clamping trigger after entering the abdominal cavity;

2.7 扳动输送扳机一次，使连发结扎夹进入钳头，通过转轮旋转调整连发结扎夹夹闭角度，将血管或管状组织置于连发结扎夹内中间或末端位置，扳动夹闭扳机扣合连发结扎夹；Pull the delivery trigger once to make the ligating clip enter the applier tip, adjust the clamping angle of the ligating clip by rotating the handwheel, place the blood vessel or tubular tissue in the middle or end position of the ligating clip, and pull the clamping trigger to fasten the ligating clip;

2.8 拨动或目视检查确认连发结扎夹在人体管腔组织的夹闭状态正常后，将连发施夹钳移离人体管腔组织；After toggle or visual inspection to confirm that the clamping state of the ligating clip in the human lumen tissue is normal, the applier is removed from the human lumen tissue;

2.9 重复“2.7,2.8”所示步骤，依次完成剩余结扎夹的输送及夹闭。Repeat the steps shown in "2.7, 2.8" to complete the delivery and clamping of the remaining ligating clips in sequence.





3.连发施夹钳使用完毕后，拉动复位帽，使之回到原位；打卡锁扣，将使用过的连发匣脱离连发施夹钳（连发匣按医疗废弃物相关规定处置）。After using the applier, pull the resetting cap to return it to its original position; punch the lock to separate the used cartridge from applier (the cartridge should be disposed of according to the relevant regulations on medical waste).



**【清洁与灭菌Cleaning and Sterilization】**

1. 冲洗 Rinse: 连发施夹钳在使用后及时用流动水冲洗, 去除器械外表面污染物; 然后连接器械冲洗阀, 初步去除器械内腔污染物, 冲洗时应扳动夹闭扳机 5 次以上, 冲洗时间应不低于 120 秒; the applier should be washed with running water in time after use to remove contaminants on the external surface of the instrument; Then connect the instrument flushing valve to initially remove the contaminants in the instrument cavity. When flushing, the clamping trigger should be pulled more than 5 times, and the 1.flushing time should not be less than 120 seconds.
2. 洗涤 Washing: 连发施夹钳冲洗后, 应使用合适的医用清洗剂浸泡器械 12~15 分钟, 再手工刷洗或超声清洗 5~10 分钟, 洗涤时密封帽应处于打开状态; After the applier is rinsed, the instrument should be soaked with a suitable medical cleaning agent for 12 to 15 minutes, and then manually scrub or ultrasonic clean for 5 to 10 minutes. The sealing cap should be open during washing.
3. 再冲洗 Rerine: 连发施夹钳洗涤后, 再用流动水按【清洁与灭菌】第 1 条冲洗的方法进行冲洗至无血渍、无污渍等残留物和锈斑; After the applier is washed, rinse with running water according to the washing method in Article 1 of 【Cleaning and Sterilization】 until there is no residue such as blood stains, stains and rust spots;
4. 终末漂洗 Final rinsing: 采用纯化水对施夹钳进行漂洗, 漂洗时间 5min; Rinsing with purified water, rinsing time 5min.
5. 干燥 Drying: 将连发施夹器放入鼓风干燥箱内, 设定温度/时间: 85℃/30min; Put the applier into the blast drying oven, set temperature/time: 85℃/30min;
6. 灭菌 Sterilization: 推荐使用高压蒸汽灭菌法进行灭菌, 具体灭菌参数如下: 灭菌设备类型为内循环排气式(下排气式), 参考压力范围 102.8kPa~122.9kPa, 灭菌温度 121℃, 最短灭菌时间 20min。It is recommended to use high pressure steam sterilization for sterilization. The specific sterilization parameters are as follows: the type of sterilization equipment is internal circulation exhaust type (lower exhaust type), the reference pressure range is 102.8kPa ~ 122.9kPa, the sterilization temperature is 121℃, and the shortest sterilization time is 20min.

**【标签、包装标识样图 Samples of labels and packaging marks】**

	使用前仔细阅读说明书 Read the instructions carefully before use
	避免日晒 Avoid the sun
	避免雨淋 Avoid rain
	非无菌提供 Non-sterile

**【储存条件、方法 Storage conditions and methods】** 储存在相对湿度不大于 80%、无腐蚀性气体、常温、清洁的室内。Store in a clean room with a relative humidity not greater than 80%, no corrosive gas, normal temperature.

**【维护保养 Maintenance】** 1.日常使用前应检查连发施夹钳的输送/夹闭扳机、输送扳机活动顺畅、钳头无明显变形/缺损; Before use, check the delivery/clamping trigger of the applier, the smooth movement of the delivery trigger, and no obvious deformation/defect of

the applicator tip;

2. 建议每年送至厂家维护保养一次； It is recommended to send it to the manufacturer for maintenance once a year;

【生产日期 Production date】见产品标签 See product label

【失效日期 Expiration date】自生产日期起使用期限 2 年，单个产品重复使用次数不超过 750 次，以先到日期为准。The use period is 2 years from the production date, and a single product cannot be reused more than 750 times. The validity period is based on which indicator is met first.

【备案人及生产企业联系方式 Contact information】电话 Tel: 0571-82862112

传真 Fax: 0571-82862332 邮编 Postal code: 310018

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